

System Level Manual Regulatory Standards Division, AMA-200

Document #

Revision

QP 217

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Title: Corrective and Preventive Action Procedure

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REVISION HISTORY			
Rev	Description of Change	Author	Effective Date
Α	Original	JLA	06/03/2003
1	Clarify Preventive and Corrective Actions	JLA	01/30/2004

REFERENCE DOCUMENTS		
Document Number	Document Title	
QMS 200	AMA-200 Quality Management System	

Documents referenced in this procedure are applicable to the extent specified herein.

1. Purpose

This procedure establishes the process to correct the cause(s) of nonconformities or potential nonconformities in products, processes, the Quality System, and/or services provided by AMA-200 in accordance with the AMA-200 Quality System Manual.

2. Scope

This procedure is applicable to all products and services governed by the requirements specified within the AMA-200 Quality System Manual.

3. Definitions and Acronyms

Corrective Action	Action taken to eliminate the cause(s) of an existing nonconformance, defect, or other undesirable situation in order to prevent recurrence
Management Representative	Person to which a Program Manager/Branch Manager reports for the action required by the QCAR
Lead Auditor	Person responsible for leading audits, processing QCARs and generating reports
Nonconformance	The non-fulfillment of a specified requirement
Preventive Action/Change in Course Design Guide (CDG)	Action taken to eliminate the cause(s) of a potential nonconformance, defect, or other undesirable situation in order to prevent occurrence. This may also be referred to as "Comprehensive Fix"
QCAR Originator	Any person within AMA-200 who identifies a nonconformance, defect, or undesirable situation and initiates a QCAR



Quality Corrective Action Request (QCAR)	Request to initiate corrective or preventive action. (QF 217)
Root Cause	Fundamental deficiency that results in a nonconformance and must be corrected to prevent recurrence of the same or similar nonconformance

4. Flowchart

There is no flowchart required for this document

5. Responsibilities

5.1 Internal Audit Program Manager (IAP) shall:

- 5.1.1 Follow-up on the progress of the corrective, preventive action to ensure that it was initiated in a timely manner,
- 5.1.2 Verify that the corrective, preventive action was completed by the specified date and that the root cause was eliminated,
- 5.1.3 If the corrective, preventive action was not completed according to the plan, investigate the cause of "failure" and take appropriate action,
- 5.1.4 Close-out the QCAR, and
- 5.1.5 Maintain a "system of records" for managing the corrective and preventive action documents, monitoring their status, and storing completed QCARs for a period of no less than five years
- 5.1.6 Assign QCAR number and update QCAR Status Log
- 5.1.7 If generated at Branch Level. provide copy of completed QCAR to the Branch,

5.2 Lead Auditor shall:

- 5.2.1 issue QCAR to the Internal Audit Program Manager for action needed,
- 5.2.2 evaluate proposed Corrective or Preventive Action Plan,
- 5.2.3 review the Comprehensive Fix to verify implementation,
- 5.2.4 review and evaluate customer comments and generate QCARs if appropriate.
- 5.2.5 train and support users of the QCAR system, as needed.

5.3 **Responsible Managers** shall:

- investigate and determine root cause(s) of nonconformities, and
- identify and implement timely corrective or preventive action.

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 Maintain a "system of records" for managing the corrective and preventive action documents, monitoring their status, and storing completed QCARs for a period of no less than five years.

5.4 **QCAR Originator** shall:

 Initiate QCAR when a need for corrective, preventive action or change to the course design guide is identified.

6. Procedure

- 6.1 The QCAR process shall be initiated whenever nonconformance is suspected or detected.
 - 6.1.1 Corrective action shall be documented using the QCAR form (QF 217) and processed in accordance with this document. Corrective action shall be initiated as a result of, but not limited to, the following:
 - 6.1.1.1 Nonconformities identified during audits.
 - 6.1.1.2 Action items from Leadership Team Reviews.
 - 6.1.1.3 Customer observations/complaints
 - 6.1.1.4 Process or product problems identified by employees
 - 6.1.2 Corrective or preventive action is not:
 - 6.1.2.1 Changes to Lesson Plans that follow the Course Design Guide
 - 6.1.2.2 Changes that do not affect the Quality Management Systems process or procedures.
 - 6.1.3 Preventive action shall be documented using the QCAR and processed in accordance with this document. Preventive action shall be determined from the analysis of appropriate data to detect trends and identify causes that may result in future nonconformities. Data sources may include, but are not limited to, the following:
 - 6.1.3.1 Internal and external audit reports
 - 6.1.3.2 Corrective, preventive action or course revision data
 - 6.1.2.3 Course revision shall comply with contract requirement (<u>AMA-260</u> <u>procedures</u>).
- 6.2 A QCAR will be processed using an electronic version. All fields must be filled out for the form to be complete.
 - 6.2.1 The QCAR Originator shall:
 - 6.2.1.1 Identify a need for corrective or preventive action.
 - 6.2.1.2 Obtain a QCAR from http://iso9000.amc.faa.gov or in Appendix 1 of QMS 200.



- 6.2.1.3 Upon completion of the appropriate blocks by the originator, it shall be forwarded to the Lead Auditor or Branch Manager.
- 6.2.2 The Lead Auditor/Branch Manager shall verify that required fields are completed. If the QCAR is not complete, the Lead Auditor/Branch Manager shall return the QCAR to the Originator for completion. The completed QCAR form shall be forwarded to the Responsible Manager.
- 6.2.3 The Responsible Manager shall review the QCAR to determine if corrective or preventive action is warranted.
 - 6.2.3.1 If corrective or preventive action is not warranted, the Responsible Manager shall identify the reason on the QCAR in the block entitled "Temporary Fix" and return it to the Lead Auditor within 10 working days.
- 6.2.4 The Lead Auditor/auditor reviews the proposed fix.
 - 6.2.4.1 Concurrence: QCAR is closed.
 - 6.2.4.2 Non-concurrence: QCAR is returned to the Responsible Manager for development of a Comprehensive Fix.
- 6.2.5 If corrective or preventive action is warranted, the Responsible Manager shall:
 - 6.2.5.1 Complete the QCAR block entitled "Temporary Fix" by identifying the immediate action required. The QCAR shall be returned to the Lead Auditor within 10 working days.
 - 6.2.5.2 Investigate and determine the root cause(s) of the nonconformance and document it on the QCAR.
 - 6.2.5.3 Develop a Comprehensive Fix to eliminate the root cause(s) of the nonconformance and document the plan in the "Comprehensive Fix" block of the QCAR.
 - 6.2.5.4 Review the Comprehensive Fix for acceptability and completeness. When satisfied, a copy of the QCAR is made available to the Lead Auditor.
 - 6.2.5.5 Implement the Comprehensive Fix to eliminate the root cause(s) of the nonconformance, using appropriate document change control procedures.
- 6.2.6 The Lead Auditor shall review the Comprehensive Fix.
 - 6.2.6.1 If the Comprehensive Fix is acceptable, a Follow-Up Audit is scheduled for verification of effectiveness.
 - 6.2.6.2 If the Comprehensive Fix is found to be effective, the QCAR is closed.

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- 6.2.6.3 If the Comprehensive Fix is not acceptable, the Lead Auditor shall return the QCAR to the Responsible Manager for re-work.
- 6.2.7 The IAP Program Manager shall review the QCAR form for completeness, close it, and file the QCAR.
- 6.2.8 Branch Managers shall maintain and record all QCARs at the Branch level and forward to the Management Representative. QCARs at the system level (Division) shall be maintained and recorded by the Lead Auditor (if found during an audit) or the Management Representative.

7. Metrics

- 7.1 Number of open Corrective / Preventive Actions that exceed their estimated closure dates.
- 7.2 Number of open Corrective / Preventive Actions that exceed their Initial Response due dates
- 7.3 QCARs shall be numbered to indicate if it is Corrective action by a preceding **C** or preventive by a preceding **P**, then year, Branch/Division, sequential number. i.e. C0325001. In this example, C would indicate Corrective action, the year is 03, the Branch is 250 and the number is 01.

Metrics for this document may be modified by the Management Review Process performed by the AMA-200 Leadership Team.

8. Quality Records

Quality Records for this document are listed in the table below. These records shall be generated and managed in accordance with AMA-200 Quality Records procedures.

Verifying Document Type or Number	Title	Retention Time
<u>QF 217</u>	Quality Corrective Action Request (QCAR)	Five Years

Quality documents, in blank form, are found in Appendix 1 of the AMA-200 QMS.